Docket: 2850 (203-3277)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:	Cunningham et al.	EXAMINER:	Melissa K. Ryckman
SERIAL NO.:	10/618,990	GROUP:	Art Unit 3773
FILED:	July 14, 2003	DATED:	January 21, 2011
FOR:	**SURGICAL COBRA HEAD SUTURE NEEDLE**		

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BRIEF ON APPEAL

Sir:

This is an appeal from a Final Office Action mailed on July 21, 2010 and an Advisory Action mailed on November 8, 2010 in the above-identified application. This Brief is accompanied by the requisite fees set forth in 37 C.F.R. §41.20(b)(2).

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being transmitted on the date below with the United States Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450, via electronic submission.

Dated: January 21, 2011

Lisa Anfuso

I. REAL PARTY IN INTEREST

The real party in interest for this application is Tyco Healthcare Group LP (d/b/a Covidien), having a principal office at 555 Long Wharf Drive, New Haven, CT 06511.

II. RELATED APPEALS AND INTERFERENCES

There are no other related prior or pending appeals or interferences for this application.

III. STATUS OF CLAIMS

The status of the claims of this application is as follows:

A) Claims 1-9, 12, 14, 15, 20-22, 24, and 25 are pending, stand rejected, and are being appealed; and

B) Claims 10, 11, 13, 16-19, 23, and 26 have been canceled.

An accurate copy of claims 1-9, 12, 14, 15, 20-22, 24, and 25 is provided in the Claims Appendix.

IV. STATUS OF AMENDMENTS

The Advisory Action mailed on November 8, 2010 indicates that the proposed amendments to the Final Office Action of July 21, 2010, filed on September 21, 2010, were entered.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1, which is hereby appealed, is directed to a surgical needle including an elongated substantially linear needle body defining a central longitudinal y-axis along which the needle body extends and transverse x and z-axes. (*See, e.g.,* Specification page 3, lines 5-6). The needle body including a central shaft portion, a first suture end portion for attachment to a suture and a second needled end portion for penetrating tissue. (*See, e.g.,* Specification page 3, lines 6-8). The needled end portion having three sides which intersect to define three cutting edges and terminate at a needle point. (*See, e.g.,* Specification page 3, lines 8-9). Each side includes one sole pair of planar surface portions arranged in oblique relation to define a general concave appearance to each side. (*See, e.g.,* Specification page 8, lines 5-9). The needled end portion further defines an enlarged transition portion adjacent the central shaft section. (*See, e.g.,* Specification page 3, lines 11-12). The enlarged transition portion defines a z-dimension "z_t" and an x-dimension "x_t", "x_t" being greater than a corresponding x-dimension "x_1" of the central shaft, wherein the z-dimension "z_t" is defined as being transversely perpendicular to the central longitudinal y-axis and extending between a first cutting edge and a second cutting edge. (*See, e.g.,* Specification page 3, lines 11-19). The x-dimension "x_t" is defined as being offset 90° from the z-dimension "z_t" and extends between a third cutting edge and a surface portion between the first cutting edge and the second cutting edge. (*See, e.g.,* FIG. 8). The needle point is displaced a predetermined distance with respect to the longitudinal axis. (*See, e.g.,* Specification page 7, lines 17-18). The predetermined distance is less than ½ the x-dimension "x_t" of the enlarged transition portion and at least one side of the needled end portion is displaced in the x-dimension "x_t" by an angle α from a plane parallel to the longitudinal axis, the angle α

being between about 2° and 10°. (*See, e.g.*, Specification at page 7, lines 15-18 and FIG. 5). The side of the needled end portion displaced by angle α from the plane parallel to the longitudinal axis has a substantially continuous slope between the enlarged transition portion and the needle point. (*See, e.g.*, FIG. 5).

Independent claim 12, which is hereby appealed, is directed to a surgical needle including an elongated needle body defining a central longitudinal y-axis along which the needle body extends and transverse x and z-axes. (*See, e.g.*, Specification page 4, lines 5-7). The needle body includes a central shaft portion, a first suture end portion for attachment to a suture and a second needled end portion for penetrating tissue. (*See, e.g.*, Specification page 4, lines 7-8). The needled end portion has three sides which intersect to define three cutting edges and terminates at a needle point. (*See, e.g.*, Specification page 4, lines 8-9). Each side includes a pair of planar surface portions arranged in oblique relation and intersects along a median plane bisecting a respective side to define a general concave appearance to the respective side. (*See, e.g.*, Specification page 4, lines 9-11 and FIG. 9). The needled end portion further defines an enlarged transition portion adjacent the central shaft section. (*See, e.g.*, Specification page 4, lines 11-12). The enlarged transition portion defines a z-dimension "z_t" and an x-dimension "x_t", "x_t" being greater than a corresponding x-dimension "x_1" of the central shaft, wherein the z-dimension "z_t" is defined as being transversely perpendicular to the central longitudinal y-axis and extending between a first cutting edge and a second cutting edge. (*See, e.g.*, Specification page 4, lines 11-17). The x-dimension "x_t" is defined as being offset 90° from the z-dimension "z_t" and extends between a third cutting edge and a surface portion between the first cutting edge and the second cutting edge. (*See, e.g.*, FIG. 8). The needle point is displaced a predetermined distance with respect to the longitudinal axis. (*See, e.g.*, Specification page 7, lines 17-18). The

predetermined distance is less than ½ the x-dimension "x_t" of the enlarged transition portion and at least one side of the needled end portion is displaced in the x-dimension "x_t" by an angle α from a plane parallel to the longitudinal axis, the angle α being between about 2° and 10°. (*See, e.g.,* Specification at page 7, lines 15-18 and FIG. 5). The side of the needled end portion displaced by angle α from the plane parallel to the longitudinal axis has a substantially continuous slope between the enlarged transition portion and the needle point. (*See, e.g.,* FIG. 5).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellants request review of the following outstanding grounds of rejection:

A) The rejection of claims 1-9, 12, 14, 15, 20-22, 24, and 25 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement; and

B) The rejection of claims 1-9, 12, 14, 15, 20-22, 24, and 25 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,403,344 to Allen ("Allen") in view of U.S. Patent No. 5,057,082 to Burchette, Jr. ("Burchette") and U.S. Patent No. 4,565,545 to Suzuki ("Suzuki").

VII. ARGUMENTS

A. Claims 1-9, 12, 14, 15, 20-22, 24, and 25 comply with the written description requirement

Claims 1-9, 12, 14, 15, 20-22, 24, and 25 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner stated in the Final Office Action that the language "each side including one sole pair of planar surface portions" is considered new matter as it is not shown in the application.

According to §2163.02 of the MPEP, "[a]n applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention."

The claimed feature, "each side including one sole pair of planar surface portions", is described in both the words of the specification and shown in the accompanying figures. As illustrated in FIGS. 8 and 9, reproduced below, and described on page 8, lines 5-9 of Appellants' specification:

> **[E]ach surface 28, 30, 32 includes a pair of surface portions 44** which intersect along a median plane "m" intersecting each surface 28, 30, 32 at a large oblique angle "d" relative to each other. (FIG. 9) The preferred angle of intersection "d" ranges from about 160° to about 175°, most preferably 170°. The intersecting surface portions 44 thus provide an overall concave or hollow ground appearance to the respective surfaces 28, 30, 32. (Emphasis added.)

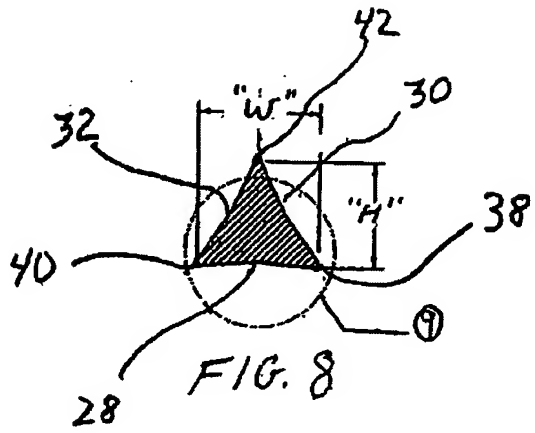


FIG. 8

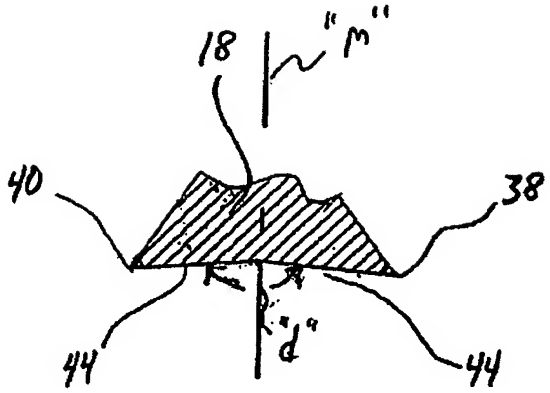


FIG. 9

Thus, the claimed recitation of "each side including one sole pair of planar surface portions" is clearly described in Appellants' specification and shown in the figures.

In the Advisory Action:

> [T]he examiner argues that Figs. 8 and 9 show one planar portion on each side (side 30 for example in Fig. 8) not one pair of planar surface portions, and page 8, ll. 5-9 of the specification states "each surface 28, 30, 32 includes a pair of surface portions 44", the specification fails to state that each surface only contains one pair of surface portions.

As reiterated by the Examiner above, the specification recites that *each surface includes a pair of surface portions*. As the angle of intersection, "d', between surface portions 44 is large (i.e., about 160° to about 175°), FIG. 9 was provided to show one of the cutting surfaces as an exemplary illustration detailing the features of each cutting surface 28, 30, 32.

Moreover, the Examiner's contention that the specification fails to state that each surface only contains one pair of surface portions is erroneous. "The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement." (MPEP §2163.02). As provided above, both the

specification and the drawings support the recitation of each surface 28, 30 and 32 including one pair of side surfaces 44.

Thus, contrary to the Examiner's position, the specification clearly describes, and the figures clearly illustrate, this feature. Accordingly, the rejection of claims 1-9, 12, 14, 15, 20-22, 24, and 25 under 35 U.S.C. §112, first paragraph, should be reversed.

B. Claims 1-9, 12, 14, 15, 20-22, 24, and 25 are patentable under 35 U.S.C. §103(a) over Allen, Burchette, and Suzuki

As the following discussion shows, the Examiner has failed to show how the prior art teaches or suggests all of the features of Appellants' independent claims 1 and 12. The combination of Allen, Burchette, and Suzuki fails to disclose or suggest the claimed surgical needles. Moreover, as discussed in detail below, Allen, Burchette, and Suzuki fail to provide any basis for concluding that the specifically recited elements should be combined to form the claimed surgical needle. Thus, the Examiner has failed to set forth a *prima facie* case of obviousness. Accordingly, the rejection of independent claim 1, and claims 2-9, 22, and 24 which depend therefrom, as well as independent claim 12, and claims 14, 15, 20, 21, and 25 which depend therefrom, should be reversed.

The patentability of two groups of claims is separately argued herein, namely the patentability of:

Claim 1, and claims 2-9, 22, and 24 which for purposes of the arguments presented are grouped together with claim 1; and

Claim 12, and claims 14, 15, 20, 21, and 25 which for purposes of the arguments presented are grouped together with claim 12.

I. Claim 1

Independent claim 1 recites, *inter alia*, a "needled end portion having three sides which intersect to define three cutting edges and terminate at a needle point, each side including ***one sole pair of planar surface portions*** arranged in oblique relation to define a general concave appearance to each side" (emphasis added).

As acknowledged in the Final Office Action, "Allen does not specify each side having one sole pair of planar surfaces." As illustrated in FIG. 4 of Allen, reproduced below, each side of Allen's needle include ***five*** planar surface portions, i.e., reference numbers 21, 21, 25, 25, and 26.

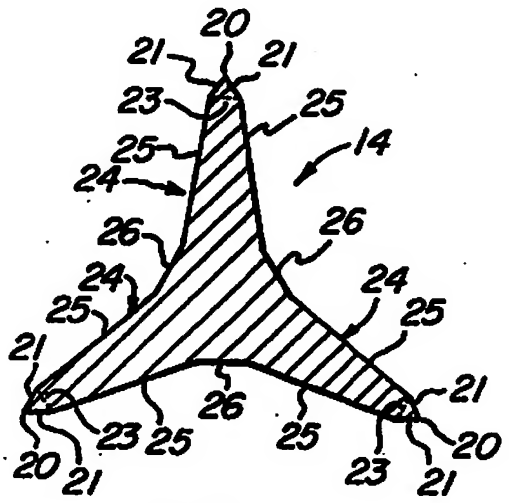


FIG. 4

Allen states that the multi-faceted cross-section "provides improved penetration performance, less trauma and distortion and a reduced wound opening area." (Allen at column 3, lines 58-60.) Allen also provides that the needle head design provides for "significant reduction in stock removal necessary to sharpen the cutting edges 20, which results in less machining time and reduced manufacturing costs." (Allen at column 3, lines 62-65.)

Burchette was relied upon, in the Final Office Action, to teach "a cutting tip with each side having one sole pair of planar surfaces." Burchette discloses a trocar assembly including a trocar tube and an obturator releasably supported within the trocar tube. The obturator includes an obturator end defined by three faces having a generally concave configuration. The Examiner asserted that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the cross section of Burchette with the device of Allen, as this is appropriate in use for specific procedures and types of tissue."

As described in Burchette, obturators are utilized "to puncture the walls of a body cavity for either draining fluid or for endoscopic procedures." (Burchette at column 1, lines 9-11.) Based upon the Examiner's rationale, the cross section of Burchette is appropriate for such use, i.e., for puncturing the walls of body cavities for draining fluid or for endoscopic procedures. Nowhere is there any disclosure or suggestion that the obturator is appropriate for use as a surgical suture needle.

Moreover, Allen teaches, with specificity, a multi-faceted cross-section to increase tissue penetration and needle sharpness of a surgical suturing needle. Accordingly, one would not look to combine Allen with Burchette and it is only with impermissible hindsight that any motivation for making a surgical needle having, among other things, "each side including one sole pair of planar surface portions arranged in oblique relation to define a general concave appearance to each side" as recited in claim 1 can be found.

In the Final Office Action, Suzuki was relied on to teach "the needle point being displaced a predetermined distance with respect to the longitudinal axis and wherein the predetermined distance is less than ½ the x-dimension "xt" of the enlarged transition portion"

and "at least one side of the needled end portion being displaced by an angle alpha from a plane parallel to the longitudinal axis, the angle alpha being between about 2° and 10° wherein the side of the needled end portion displaced by angle alpha from the plane parallel to the longitudinal axis has a substantially continuous slope between the enlarged transition portion and the needle point" (citations and parenthetical notations omitted).

Suzuki fails to cure the deficiencies of Allen and Burchette as Suzuki fails to teach a "needled end portion having three sides which intersect to define three cutting edges and terminate at a needle point, each side including one sole pair of planar surface portions arranged in oblique relation to define a general concave appearance to each side," as recited in claim 1.

Additionally, there is no motivation to combine Allen with Suzuki. Suzuki discloses a catheter insertion device used for percutaneous insertion of a catheter into an artery or a vein located in a deep part of a tissue. The catheter insertion device includes an inner needle including a taper portion and a beveled surface at its distal end. The Examiner asserted that "it would have been obvious to one of ordinary skill in the art to use the geometry of Suzuki with the device of Allen, as the angle blade ***increases the surface area*** of the blade and aids in cutting the tissue" (emphasis added).

As stated above, however, the needle head of Allen is shaped so that the only portion that substantially contacts tissue during cutting is the three cutting edges to improve penetration performance, lessen tissue trauma and distortion, and reduce the wound opening area. Thus, increasing the surface area of Allen's needle, as suggested by the Examiner, is contrary to the teachings of Allen and would change the principle of operation of Allen.

According to §2143.01(VI) of the MPEP, the proposed modification cannot change the

principle of operation of a reference -- "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious."

Therefore, Allen, Burchette, and Suzuki, alone or in combination, fail to teach or suggest all of the limitations of claim 1.

In view of the foregoing, Appellants respectfully request that the rejection of claim 1, and claims 2-9, 22, and 24 which depend therefrom, under 35 U.S.C. §103(a) over Allen in view of Burchette, and Suzuki be reversed.

II. Claim 12

The arguments presented above with respect to claim 1 apply with equal force to claim 12. In summary, it is the Appellants' position that the Examiner has failed to present a *prima facie* case of obviousness and has improperly combined Allen with Burchette, and Suzuki to form the present rejection.

Claim 12 differs from claim 1 in that claim 12 requires, *inter alia*, "each side including a pair of planar surface portions arranged in oblique relation and intersecting along a median plane bisecting a respective side to define a general concave appearance to the respective side."

In the Final Office Action, it was asserted that Allen discloses "each side including a pair of planar surface portions arranged in oblique relation to define a general concave appearance to each side (Fig. 4)."

However, as noted above, and as shown with reference to FIG. 4 of Allen above, Allen fails to disclose this feature including a pair of planar surface portions that intersect along a

median plane that bisects a respective side. Moreover, the Examiner has not articulated which features of Allen have been interpreted to be any of the claimed features.

Burchette and Suzuki fail to cure the deficiencies of Allen. Neither Burchette nor Suzuki discloses or suggests "each side including a pair of planar surface portions arranged in oblique relation and intersecting along a median plane bisecting a respective side to define a general concave appearance to the respective side," as recited in claim 12.

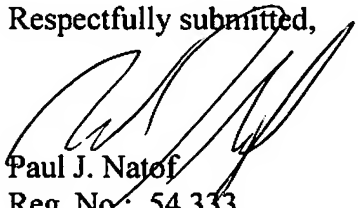
Moreover, Applicants maintain the arguments set forth above regarding the improper combination of Allen with Burchette and Suzuki. Therefore, Allen, Burchette, and Suzuki, alone or in combination, fail to teach or suggest all of the limitations of claim 12.

In view of the foregoing, Appellants respectfully request that the rejection of claim 12, and claims 14, 15, 20, 21, and 25 which depend therefrom, under 35 U.S.C. §103(a) over Allen in view of Burchette and Suzuki be reversed.

C. Conclusion

In view of the foregoing remarks, Appellants respectfully submit that all of the claims pending in this application are in condition for allowance. Early and favorable reconsideration of this appeal is respectfully requested.

Respectfully submitted,



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VIII. CLAIMS APPENDIX

1. A surgical needle, which comprises:

an elongated substantially linear needle body defining a central longitudinal y-axis along which the needle body extends and transverse x and z-axes, the needle body including a central shaft portion, a first suture end portion for attachment to a suture and a second needled end portion for penetrating tissue, the needled end portion having three sides which intersect to define three cutting edges and terminate at a needle point, each side including one sole pair of planar surface portions arranged in oblique relation to define a general concave appearance to each side, the needled end portion further defining an enlarged transition portion adjacent the central shaft section, the enlarged transition portion defines a z-dimension "z_t" and an x-dimension "x_t", "x_t" being greater than a corresponding x-dimension "x_1" of the central shaft, wherein the z-dimension "z_t" is defined as being transversely perpendicular to the central longitudinal y-axis and extending between a first cutting edge and a second cutting edge, and wherein the x-dimension "x_t" is defined as being offset 90° from the z-dimension "z_t" and extending between a third cutting edge and a surface portion between the first cutting edge and the second cutting edge;

the needle point being displaced a predetermined distance with respect to the longitudinal axis and wherein the predetermined distance is less than ½ the x-dimension "x_t" of the enlarged transition portion; and

at least one side of the needled end portion being displaced in the x-dimension "x_t" by an angle α from a plane parallel to the longitudinal axis, the angle α being between about 2° and 10°, wherein the side of the needled end portion displaced by angle α from the plane

parallel to the longitudinal axis has a substantially continuous slope between the enlarged transition portion and the needle point.

2. The surgical needle according to claim 1 wherein the planar surface portions of each side are arranged to intersect along a median plane bisecting a respective side to define a substantially symmetrical concave appearance to the respective side.

3. The surgical needle according to claim 1 wherein the enlarged transition portion defines a z-dimension "z_t" greater than a corresponding z-dimension "z_l" of the central shaft portion.

4. The surgical needle according to claim 3 wherein the x-dimension "x_t" and the z-dimension "z_t" correspond to the height and width respectively of the transition portion of the needled end portion.

5. The surgical needle according to claim 1 wherein the planar surface portions of each side intersect to define an included angle ranging from about 160° to about 175°.

6. The surgical needle according to claim 5 wherein the included angle is about 170°.

7. The surgical needle according to claim 1 wherein two of the cutting edges intersect at the needle point and define an angle of about 22° to about 25°.

8. The surgical needle according to claim 1 wherein the central shaft portion defines a distal shaft transition portion adjacent the needled end portion, the distal shaft portion defining a cross-section of general triangular character.

9. The surgical needle according to claim 8 wherein the distal shaft portion includes three planar surfaces interconnected by rounded surfaces.

10-11. (Canceled)

12. A surgical needle, which comprises:

an elongated needle body defining a central longitudinal y-axis along which the needle body extends and transverse x and z-axes, the needle body including a central shaft portion, a first suture end portion for attachment to a suture and a second needled end portion for penetrating tissue, the needled end portion having three sides which intersect to define three cutting edges and terminating at a needle point, each side including a pair of planar surface portions arranged in oblique relation and intersecting along a median plane bisecting a respective side to define a general concave appearance to the respective side, the needled end portion further defining an enlarged transition portion adjacent the central shaft section;

wherein the enlarged transition portion defines a z-dimension "z_t" and an x-dimension "x_t", "x_t" being greater than a corresponding x-dimension "x_1" of the central shaft, wherein the z-dimension "z_t" is defined as being transversely perpendicular to the central longitudinal y-axis and extending between a first cutting edge and a second cutting edge, and wherein the x-dimension "x_t" is defined as being offset 90° from the z-dimension "z_t" and

extending between a third cutting edge and a surface portion between the first cutting edge and the second cutting edge;

the needle point being displaced a predetermined distance with respect to the longitudinal axis and wherein the predetermined distance is less than ½ the x-dimension "x_t" of the enlarged transition portion; and

at least one side of the needled end portion being displaced in the x-dimension "x_t" by an angle α from a plane parallel to the longitudinal axis, the angle α being between about 2° and 10°, wherein the side of the needled end portion displaced by angle α from the plane parallel to the longitudinal axis has a substantially continuous slope between the enlarged transition portion and the needle point.

13. (Canceled)

14. The surgical needle according to claim 12 wherein the enlarged transition portion "z_t" at least substantially equal to a corresponding z-dimension "z_l" of the central shaft.

15. The surgical needle according to claim 14 wherein the enlarged transition portion "z_t" is greater than the corresponding z-dimension "z_l" of the central shaft portion.

16 -19. (Canceled)

20. The surgical needle according to claim 15 wherein each side of the needled end portion includes a single pair of first and second planar surface portions arranged in oblique

relation, the first and second planar portions being the pair of planar portions.

21. The surgical needle according to claim 12 wherein each side of the needled end portion includes a single pair of first and second planar surface portions arranged in oblique relation, the first and second planar portions being the pair of planar portions.

22. The surgical needle according to claim 1 wherein each cutting edge is substantially linear.

23. (Canceled)

24. The surgical needle according to claim 1 wherein the needle body is adapted to assume a curved configuration.

25. The surgical needle according to claim 12 wherein each cutting edge is substantially linear.

26. (Canceled)

IX. EVIDENCE APPENDIX

None

X. RELATED PROCEEDINGS APPENDIX

None